## **Opening Remarks & Leadership Update**

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# **Epi Picture**

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## **Vaccine Update**

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# NC DHHS COVID-19 Vaccine Program LHD Update

February 8, 2022







# **AGENDA**

Slide #	Topic
3	Status of Vaccine Approval
4	0-4 Approval Timeline
5	0-4 Demand Planning
6	0-4 Product Handling & Pfizer COVID-10 Vaccine Products
7	Distribution Wave 1
8	Distribution Wave 2 and Beyond
9	Distribution and Ordering Visual
10	Call to Action & Opportunity to Connect
11	Pediatricians and Vaccine Hesitancy
12	Local Data Planning Resources
13	What to Expect From DHHS
14	What You Can Do

## STATUS OF COVID-19 VACCINE AUTHORIZATION IN US: 2/07/2022

			Pediatrics						
	Adults 18 +	16-17	12-15	5-11	6 months - 5 years		Additional Dose (Immunocompromised)	Booster*	
Pfizer	Approved (August '21)	Approved (August '21)	EUA (May '21)	EUA (May '21)	Under Review (Feb '22)		EUA for 5+ yrs (Aug '21 – Jan '22)	EUA for those 12+ yrs at 5+ months	
moderna	Approved (Jan '22)	Under Review (June '21)	Under Review (June '21)	-	-		EUA for 18+ (Aug '21)	EUA for those 18+ yrs at 5+ months	
Janssen  PHARMACEUTICAL COMPANIES  OF Johnson-Johnson	EUA (Feb '21)	-	-	-	-		N/A	EUA for those 18+ yrs at 2+ months	
ocugen	<del>-</del>	Under Review (Nov '21)	Under Review (Nov '21)	Under Review (Nov '21)	Under Review for 2+ yrs. (Nov '21)				
novavax	Under Review (Jan '22)								



#### 0-4 APPROVAL TIMELINE

Clinical trial and/or real-world data

Vaccines and Related Biological Products Advisory Committee (VRBPAC)

FDA

Advisory
Committee on
Immunization
Practices (ACIP)

CDC

**Public** 













Pfizer submits an EUA application for <5 year olds

(Submitted 2/2)

VRBPAC (may) meet. If so, they assess the safety and effectiveness data. And vote to recommend (or not) the vaccine FDA makes a decision

ACIP meets to assess safety and effectiveness. But most importantly will decide policy of implementation. Then vote.

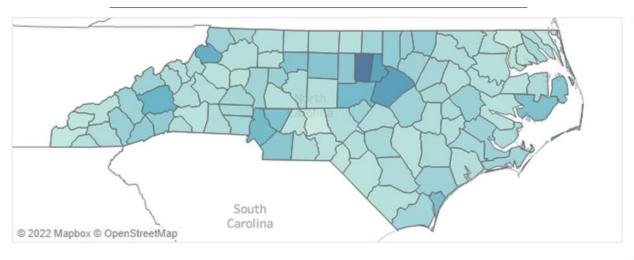
CDC makes a decision

Vaccine in arms

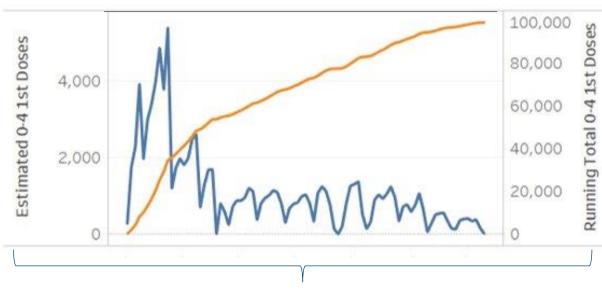
### 0-4: DEMAND PLANNING

- The 6 month-4-year-old population is 609,770 children.
- State market research expects 52% to get the vaccine.
- Current projections show 16-19% of the under 5 population will be vaccinated within 3 months = 95,116 first doses.
- Week 1 demand will be 20-30K.

#### **Estimated Vaccination Rate by County**



#### Estimated 1<sup>st</sup> doses (by day & running total)



First 3 Months



### 0-4 PRODUCT HANDLING

#### Pfizer-BioNTech COVID-19 Vaccine Products

#### PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL; CDC DOCUMENT – SHARED FOR JURISDICTIONAL PLANNING PURPOSES ONLY

	Current P	roducts	<b>Future Product</b>	
Age Indications <sup>a</sup>	12 years and older	5 through 11 years	6 months through 4 years <sup>d</sup>	
Vial Cap Color and Label with Color Border	GRAY	ORANGE	MAROON	
Preparation	Do Not Dilute	Dilute Before Use	Dilute Before Use	
Amount of Diluent Needed per Vial <sup>b</sup>	Do Not Dilute	1.3 mL	2.2 mL	
Dose Volume/Dose	0.3 mL/ <b>30 mcg</b>	0.2 mL/ <b>10 mcg</b>	0.2 mL/ <b>3 mcg</b>	
Doses per Vial	6 doses per vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)	
	×	Storage Conditions		
ULT Freezer (-90°C to -60°C)°	9 months	9 months	9 months	
Freezer (-25°C to -15°C)	DO NOT STORE	DO NOT STORE	DO NOT STORE	
Refrigerator (2°C to 8°C)	10 weeks	10 weeks	10 weeks	
Room Temperature (8°C to 25°C)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)	
After First Puncture (2°C to 25°C)	Discard after 12 hours	Discard after 12 hours	Discard after 12 hours	

<sup>\*</sup>Use the appropriate product based on the age of the recipient.

- The product will have a Maroon top
- Minimum Order Quantity: 100 dose orders; 10 dose vials.
- The 0-4 product requires 2.2mL diluent this is different than the 5-11 product.
- Ultra-Cold Freezers are not necessary for a provider to offer Pfizer pediatric vaccine - The new pediatric formulation will be able to be stored in the fridge for up to 10 weeks.

Download the updated Pfizer product guide,

<sup>&</sup>lt;sup>b</sup> Diluent: Sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

Regardless of storage condition, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons.

The vaccine is currently under emergency use authorization review by the Food and Drug Administration (FDA) for children 6 months through 4 years old.

## **VACCINE DISTRIBUTION**

The product will ship initially in 2 waves. Shipments will start to ship as soon as an FDA EUA issued for the product.

### Wave 1: Product Launch/Pre-Orders

- NCDHHS will use a "push" model to distribute the Pfizer 0-4 vaccine to Local Health Departments and Vaccine for Children Sites. **Selected sites will receive allocation notifications starting February 8, 2022.** 
  - •There are 57,800 doses available for NC in the Wave 1 product launch. Not all providers will be allocated product for this wave.

#### Allocation Methodology:

- •Each of the 100 counties will be allocated doses based on the eligible population size.
- •County vaccine allotments will be modified with expected demand input generated with data from the 5-11 program.
- •Significant differences in vaccination rates between counties will also inform the allocation strategy.
- •Vaccine will be allocated to Local Health Departments and Vaccine for Children Locations based on the percentage of the 5-11 administrations for their given county.
- The first wave is projected to deliver vaccines starting February 21, 2022 Vaccine Locations must be able to receive the vaccine on the President's Day Holiday

- NCDHHS is committed to offering this vaccine in a way that is fast, fair and everywhere. Therefore, we will lead with equity by ensuring that our Local Health Departments and Vaccine For Children Providers have immediate access to vaccine.
- It is expected that the Local Health Department will accept this push allocation, as they are the only provider type in NC that serves all 100 counties.
- Local Health Departments may transfer vaccines locally as they see fit to support local effort to ensure a "fast, fair, and everywhere" vaccine program.

Allocation Responses are due by Thursday, February 10th at 10 am

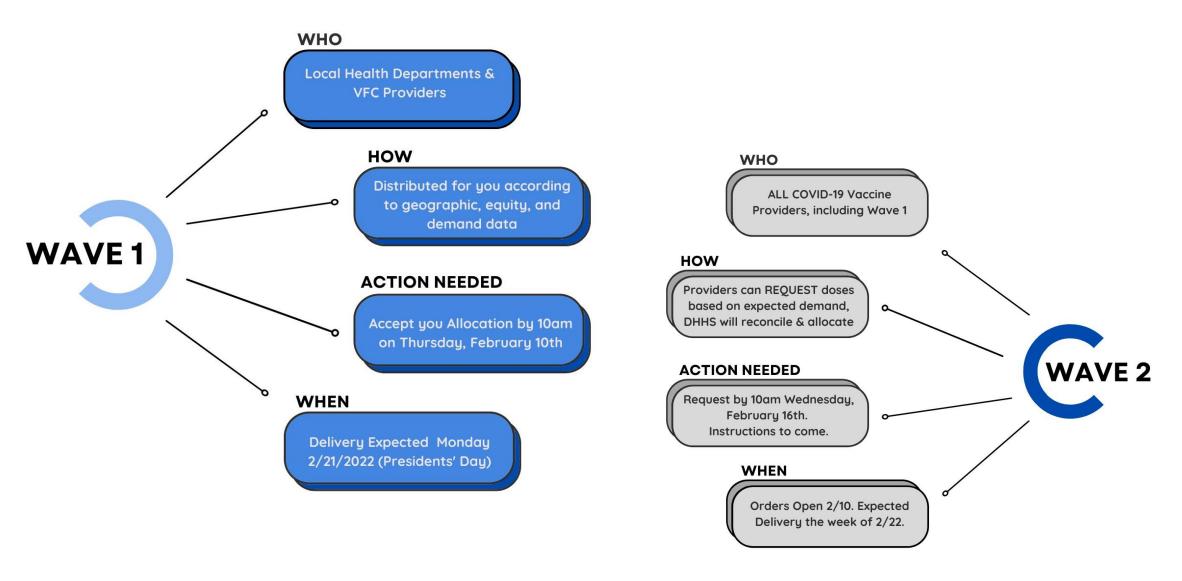
## **VACCINE DISTRIBUTION**

## Wave 2: Post Program Launch

- NCDHHS will use a "pull" model to distribute requested 0-4 Pfizer vaccine to all Enrolled Vaccine Providers.
  - Providers will be able to request vaccine beginning **Thursday, February 10th** for Wave 2.
  - •Submission is due by Wednesday, February 16th @ 10am.
  - •It is estimated that 57,800 doses will be available for the Wave 2 post-product launch. This will be confirmed with our federal partners at a later date.
  - Order Threshold Methodology:
    - All orders requests will be reviewed and modified to ensure that vaccine is shipped to appropriate locations based on the eligible county population and expected vaccine demand.
    - DHHS will distribute product according to demand, capacity, and equity data.
    - All enrolled COVID-19 Vaccine Providers are eligible for requesting vaccine
- The second wave is projected to start delivering vaccines starting February 22, 2022 but they may arrive throughout the week.

#### **Beyond:**

- The Provider Ordering Guidance will be updated at a later date to explain how future supply can be obtained.
- Providers are responsible for ordering vaccine for 2nd doses, and potentially 3rd doses if authorized.



Providers are responsible for ordering 2nd, and 3rd doses if applicable.

The Ordering Guidance will be updated at a later date.



# LHDs are the only providers present in all 100 counties

You will be a lynchpin in broad access to vaccine for this age group!

NCDHHS wants to understand your existing outreach program work and community collaborations that can be leveraged to better inform State planning. We are asking for LHD subject matter experts to participate in a stakeholder planning discussion - especially from program areas that have active connections with target recipients and current/potential vaccine providers such as:

- CMARC
- Childcare Health Consultant
- Pregnancy Care Managers
- NFP

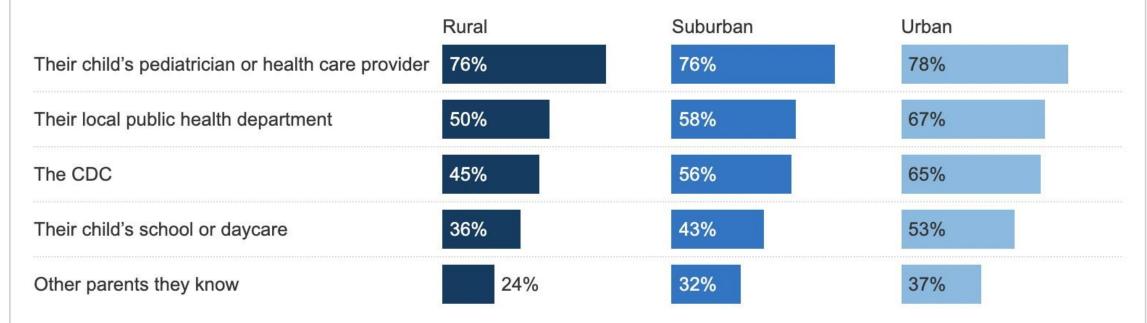
- WIC
- Immunization Managers
- Health Educators
- COVID vaccine operations.

Please send recommended staff names and contact information through your NCALHD Regional Representative to Kimberly.McDonald@dhhs.nc.gov

Figure 9

# Pediatricians Are Top Trusted Source Of Child Vaccine Information For Parents Across Community Types

Percent of parents who say they trust each of the following a great deal or a fair amount to provide reliable information about the COVID-19 vaccines for children:

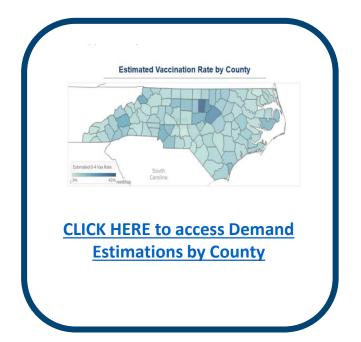


NOTE: Among parents or guardians of children under 18. See topline for full question wording. SOURCE: KFF COVID-19 Vaccine Monitor: Winter Update on Parents' Views (November 8-23, 2021) • Download PNG

Vaccine Monitor

## **LOCAL DATA RESOURCES**





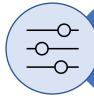




## 0-4: WHAT YOU CAN EXPECT FROM US



Forecasting Potential Provider Capacity



Guidance for future vaccine distribution/ordering





Anticipated County-specific <5 demand rates



Visual aid resources to prepare



Providing increased opportunities to connect and ask questions with DHHS



Vaccine distribution information by county



Resources to counsel vaccine-hesitant families



Offering provider support for NCIR/CVMS to ensure ease of documentation

# What You Can Do:

## 1) Accept your Wave 1 Allocation

As soon as possible, and no later than Thursday, February 10 @ 10am

- 2) Check in with the providers in your area.
  - Are they enrolled in the COVID-19 vaccine program? Share our <u>Become an</u> <u>Under 5 Vaccine Provider</u> broadly (especially with pediatric providers!)
  - Should they consider extended or weekend hours during the initial wave of under 5 vaccines?
- 3) Send recommended focus group staff names and contact info
- to Kimberly.McDonald@dhhs.nc.gov

# **Testing**

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# **Contact Tracing**

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In this pandemic moment, vaccine, testing, and masking are best practices to prevent viral spread. CI/CT are important tools but less effective in reducing transmission outside of congregate settings.

#### **CI/CT** prioritization

- Outreach to all case patients continues through texts and email
- Do case investigation and contact tracing for priority groups 1 and 2: these are outbreaks/clusters reported to you, in congregate living, or working in or potentially exposed in certain high density settings.

Prioritizing case phone outreach ensures that *priority* cases are investigated in a timely way, and that diagnosis notification and support for under resourced populations is not interrupted.

- As staff are available, make phone calls to case patients to provide information and resources (no case investigation/contact tracing) for groups 3 and 4:
  - General public whose text is not delivered
  - People in under resourced communities
- Contact tracing call center is available to case patients and contacts; phone number for call center is in emails and texts
- Flex CI/CT staff to support vaccine and testing duties as needed
- Use efficient NC COVID strategies to move cases through workflows- Data Entry support available through CCTC (email nmatyas@carolinactc.org for Data Entry support)

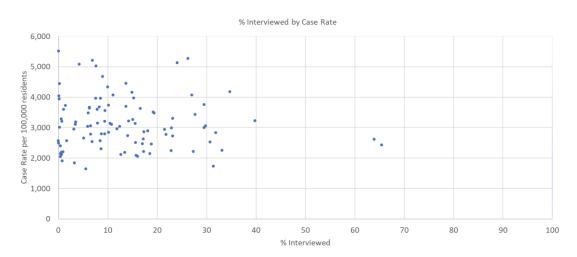




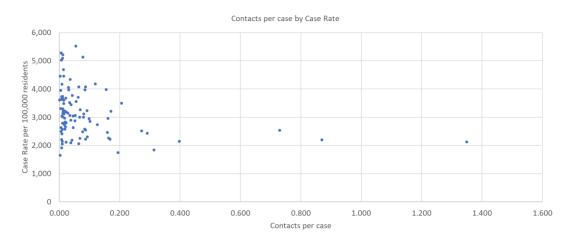
## Current CI/CT data

#### Most LHDs are interviewing a subset of case patients; contact tracing is limited





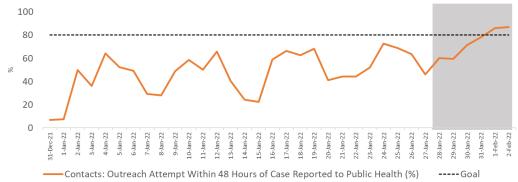
Contacts per case by weekly case rate for all counties (data from Dec. 31st to Feb. 2nd).



Although some outreach was delayed at the peak of this wave, most outreach is timely 84% of case patients are electronically notified



—Of cases Electronically Notified, Electronically Notified within 24 hours





---- Goal

# **IP Guidance Updates**

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## Updated CDC Guidance for Long-term Care Facilities

# Testing

#### Create a Plan for Testing Residents and HCP for SARS-CoV-2

- FDA evaluates test characteristics and facilities should be aware of how tests perform for circulating variants.
- Anyone with even mild symptoms of COVID-19, regardless of vaccination status, should receive a viral test as soon as
  possible.
- Newly-admitted residents and residents who have left the facility for >24 hours, regardless of vaccination status, should have a series of two viral tests for SARS-COV-2 infection; immediately and, if negative, again 5-7 days after their admission.
- Asymptomatic residents with close contact with someone with SARS-CoV-2 infection, regardless of vaccination status, should have a series of two viral tests for SARS-CoV-2 infection. In these situations, testing is recommended immediately (but generally not earlier than 24 hours after the exposure) and, if negative, again 5–7 days after the exposure.
- In general, testing is not necessary for asymptomatic people who have recovered from SARS-CoV-2 infection in the
  prior 90 days; however, if testing is performed on these people, an antigen test instead of a nucleic acid amplification
  test (NAAT) is recommended. This is because some people may remain NAAT positive but not be infectious during
  this period.



# Updated CDC Guidance for Long-term Care Facilities

# Manage Residents with Close Contact

Manage Residents who had Close Contact with Someone with SARS-CoV-2 Infection

- Residents who are not up to date with all recommended COVID-19 vaccine doses and who have had close contact
  with someone with SARS-CoV-2 infection should be placed in quarantine after their exposure, even if viral testing is
  negative. HCP caring for them should use full PPE (gowns, gloves, eye protection, and N95 or higher-level respirator).
  - Residents can be removed from Transmission-Based Precautions after day 10 following the exposure (day 0) if they do not develop symptoms. Although the residual risk of infection is low, healthcare providers could consider testing for SARS-CoV-2 within 48 hours before the time of planned discontinuation of Transmission-Based Precautions.
- Residents can be removed from Transmission-Based Precautions after day 7 following the exposure (day 0) if a viral
  test is negative for SARS-CoV-2 and they do not develop symptoms. The specimen should be collected and tested
  within 48 hours before the time of planned discontinuation of Transmission-Based Precautions.

Nursing Home and LTCF Guidance: <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html</a>
Infection Prevention for Healthcare Personnel Guidance: <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html</a>



## Guidance Reminders for Long-term Care Facilities

## **Visitors**

- Even if they have met <u>community criteria</u> to discontinue isolation or quarantine, visitors **should not visit** if they have any of the following **and have not met the same criteria used to discontinue isolation and quarantine for residents** (typically until 10 days after last exposure or onset of symptoms):
  - a positive viral test for SARS-CoV-2,
  - symptoms of COVID-19, or
  - close contact with someone with SARS-CoV-2 infection

## **COVID Units**

- Some facilities may face circumstances where a dedicated COVID-19 unit is not feasible. When large numbers of residents are
  actively infected and there are staffing shortages that prevent dedicating staff to a COVID unit, it may be safer to care for
  residents in their current location in order to minimize movement and room changes.
- LHDs and facilities are encouraged to assess relevant factors and individual facility capabilities to determine the safest options for facility residents and staff.

Nursing Home and LTCF Guidance: <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html</a>
Infection Prevention for Healthcare Personnel Guidance: <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html</a>



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## **NC COVID Reminders**

- We understand there are a lot of events in your workflows and you are trying to clear it out. Please refer
  to the documents on the CD manual under NC COVID on how to report events to the state (with case
  interview and without case interview).
- Please remember that for NC COVID when you submit an event to the State, the classification status should match the lab result. For example, if the person has only an Antigen result, please submit to the State with the classification status as probable.
- We are seeing users have some difficulty entering At Home tests, we have a job aid to help with this located on our training materials page
- The link to the NC COVID page is on the NC COVID log in page as well, in the notes section on the left.
- We have split the workflows and refreshed all of them at this point.
- Reminder for reports, please run reports in small batches. We have had many LHDs running large
  reports that make the system run sluggish and IT has had to re-start the servers. Please be mindful of
  all the users and try to run reports in 1-2 week timeframes depending on the size of your county.
- Trainings are still ongoing for NCEDSS basic and NC COVID, when requesting trainings supervisors
  please include the name and email address for the participants. Please email
  NCEDSStrainings@dhhs.nc.gov
  - There will be focused webinar on Thursday Feb 10 on Interstate Notifications where the helpdesk/training staff will be available to answer questions.



Q&A

